REMARKS

Claims 1, 4-24, 28-39, 67-69 and 72-81 are currently pending in the above-identified application. Claims 2-3, 25, 70 were previously canceled. Applicant confirms that claims 25-26, 40-66 and 71 are also canceled. Claims 9 and 35 is newly canceled. Claims 1, 4, 9, 11, 12, 18, 20 22, 23, 31, 36, 39, 67, and 79-81 have been amended. No new matter has been added.

Examiner Interview of April 6, 2004

Applicants thank Examiners Nguyen and Milano for the kind and courteous interview of April 6, 2004. In the interview, Applicants discussed independent claim 1 in light of Passafaro et al. and Adams. It was agreed that the proposed claim amendments to independent claim 1 distinguished the claims over the cited references. Applicants have made similar changes to the other independent claims. The Examiner will perform an additional search on the amended claims.

Claim Rejections under 35 U.S.C. §103(a) over Adams (6,312,438)

Claims 1, 4-24, 28-39, 67-69 and 72-81 are rejected under 35 U.S.C. §103(a) as being unpatentable over Adams. Such rejections are traversed in part and overcome in part.

To expedite prosecution of the present application, Applicants have amended claim 1. Applicants herein reserve the right to pursue the subject matter of original independent claim 1 in continuation or continuation-in-part patent applications.

Amended claim 1 provides an assembly for crossing occlusive or stenotic material. The assembly comprises a guidewire comprising an axial passage, an outer diameter between approximately 0.009 inches and 0.035 inches, and a torqueability and pushability to be advanced through a vascular body lumen without the need of a separate guidewire. A housing is

removably coupled to a proximal end of the flexible, hollow guidewire. A drive shaft rotatably and translatably extends through the axial passage of the guidewire. The drive shaft comprises a distal tip that can be rotated and advanced to create a path that is larger than the outer diameter of the guidewire through the occlusive or stenotic material.

It is well settled that in order to establish a *prima facie* obviousness under 35 U.S.C. § 103(a), the Examiner must establish *inter alia* that the prior art references teach or suggest all of the claim limitations and that there be some suggestion or motivation to one of ordinary skill in the art for the proposed combination so as to produce the claimed invention. *See* MPEP §2143.

The present claims are explicitly limited to a flexible, hollow guidewire. It is well settled that claims must only be interpreted as broadly as their terms reasonably allow and it is well settled that words of a claim must be given their plain meaning. The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999). *See* MPEP § 2111.01.

The ordinary meaning to a person of ordinary skill in the art and the intrinsic evidence in the present application goes against the Examiner's unduly broad interpretation of the term "guidewire " to encompass the elongate outer member 12 (and/or rigid out tube 18 of Adams) (*See* col. 4, lines 44-53). Nothing in Adams suggests that the outer member 12 is a guidewire, nor is there any suggestion for the outer diameter sizes required by independent claim 1.

Specifically, the 27th Edition of Stedman's Medical Dictionary (Lippincott Williams & Wilkins 2000), a copy of which is attached herewith, defines a "guidewire" as follows:

> "guidewire: A wire or spring used as a guide for placement of a larger device or prosthesis, such as a catheter or intra-medullary pin."

The dictionary definition states that a guidewire is generally used as a guide for placement of a larger device, such as a catheter. Adams' rigid outer tube 18 is not a guidewire, as the term is used in the art. In contrast, Adams' instrument appears to be a handheld instrument that comprises a rigid outer tube 18 that would be incapable of guiding another instrument. There is simply no description or suggestion of a structure that resembles a guidewire or that Adams rigid outer tube may be used to guide a larger device.

The intrinsic evidence in Applicants' specification is consistent with the dictionary definition of the term "guidewire" and further shows that Adams' elongate outer member 12 or rigid outer tube 18 is not a guidewire. Specifically, as is stated in U.S. Patent 6,059,767, which was incorporated by reference into the Applicant's present application, a guidewire is generally used to "provide columnar strength to the catheter and is therefore used to guide and position conventional prior art catheters at target tissue sites." (*See the '767 patent* at col. 5, lines 10-14). Furthermore, as noted in the background of the Applicants' application at page 1, lines 22-31, a guidewire may be used to position a catheter at the lesion. However, if the lesion is total or near total, it may be difficult or impossible to initially place a guidewire across the lesion.

Under the plain meaning of "guidewire" and the intrinsic evidence in the present application, a person of ordinary skill in the art would not reasonably interpret the elongate outer member 12 or rigid outer tube 18 to be a "guidewire" that is encompassed by the claims of the present invention.

In the office action, the Examiner stated:

> "The system of Adams could be made a guidewire that has a passage with an outer diameter between 0.009 inches and 0.035 inches. It has been held that changes in size only require routine skill in the art."

The mere fact that the rigid outer tube 18 can be modified into a guidewire is not sufficient to establish *prima facie* obviousness (MPEP §2143.01). There must be some suggestion to modify Adams into a guidewire. However, nothing in Adams suggests the

desirability that the burring instrument be a guidewire with the claimed dimensions. In fact, Applicants submit that Adams instrument appears to be incapable of performing as a guidewire. First, the outer tube 18 is rigid and is configured to allow for surgical removal of bone from a patient's nasal front beak (col. 10, lines 190-21). The rigid Adams burring instrument would not appear to be capable of being advanced through tortuous vascular body lumens.

Second, in order for a second device to be guided over the rigid outer tube 18 of Adams, the proximal outer hub 16 would have to be removable, otherwise, practically speaking, the second device would not be able to be guided over the outer tube 18 and into the target vascular body lumen. Applicants have amended independent claim 1 to receive a housing that is removably coupled to a proximal end of the flexible, hollow guidewire. Nothing in Adams suggests that the proximal hub 16 is removable.

Furthermore, independent claim 1 has been amended to recite that the distal tip creates a path that is larger than the outer diameter of the guidewire through the occlusive or stenotic material. Such a distal tip is not described by Adams. In contrast, Adams shows in Figure 1 that the bur tip 36 and inner tube 34 are inserted through a proximal end of the rigid outer tube 18 and advanced out of the distal end. Consequently, the bur tip 36 must have a diameter that is smaller than the outer diameter of the rigid outer tube, otherwise it could not be advanced through the outer rigid tube 18. Consequently, Adams also fails to describe or suggest that the distal tip creates a path that is larger than the outer diameter of the guidewire, as is required by claim 1.

The Examiner's determination that the elongate outer member 12 is a guidewire is not a reasonable interpretation of the term "guidewire" and claim 1 of the present invention should be allowable over Adams. Furthermore, Adams fails to describe a distal tip that creates a path that is larger than the outer diameter of the guidewire. Consequently, independent claim 1 is allowable. For at least the same reasons, dependent claims 2-19 are also allowable.

Since independent claims 67, 80, and 81 also provide similar structure (e.g., flexible guidewire with a drive shaft in a passage of the guidewire and a housing removably

coupled to the proximal end of the guidewire), such independent claims are also allowable over Adams. For at least the same reasons, dependent claims 68-70 and 72-79 are also allowable over Adams.

Independent claim 20 provides a guidewire system for passing through an occlusion or stenosis. The system comprises a flexible, hollow guidewire having a steerable distal end, a proximal end, and a lumen therebetween. A drive shaft is movably disposed within the hollow guidewire. The drive shaft has a longitudinal axis, a proximal end, and a distal tip portion. A rotating mechanism is removably coupled to the proximal end of the drive shaft. An actuator is coupled to the drive shaft for controlling the axial movement of the drive shaft. Activation of the actuator advances the drive shaft from a retracted position to an extended position. The rotating distal tip portion in an extended position can create a path through the occlusion or stenosis. Such a guidewire system is not described or suggested by Adams.

Claim 20 is allowable over Adams for at least three reasons. First, similar to claim 1 (as described above), Adams does not show a flexible, hollow guidewire with a drive shaft disposed within the hollow guidewire.

Second, while Adams describes a handpiece motor that rotates the inner member 14 at col. 10, lines 1-4, the Examiner has not shown where Adams describes or suggests an actuator coupled to the drive shaft for controlling the axial movement of the drive shaft and that the drive shaft is moveable between a retracted position and an extended position. The portion of Adams specification referred to by the Examiner merely refers to rotating the inner member 14.

Third, the Examiner has not shown where Adams describes or suggests a steerable distal end. Adams merely shows an angled distal end. As is described on page 10, line 25 to page 11, line 12 of the originally filed specification, the steerable distal end may be deflected while in the body lumen to provide greater intraluminal control during the procedure. Such a steerable distal end is not described or suggested by Adams.

For at least these reasons, independent claim 20 is also allowable over Adams. For at least the same reasons, dependent claims 21-30 are also allowable.

Amended claim 31 recites a system for crossing an occlusion or stenosis within a body lumen. The system comprises a flexible, hollow guidewire having a proximal end, a distal end, and an axial passage extending to a distal tip at the distal end. A drive shaft is rotatably and translatably receivable in the axial passage of the guidewire. A housing is removably coupled to the proximal end of the flexible, hollow guidewire. A flattened and twisted distal tip is attached to the drive shaft that can create a path in front of the elongate member, wherein the drive shaft and distal tip are moveable between an axially retracted configuration and an axially extended configuration.

Such a system is allowable over Adams for at least two reasons.

First, as noted above, Adams does not describe or suggest a flexible hollow guidewire with a drive shaft in the axial passage of the guidewire and a housing removably coupled to the proximal end of the flexible, hollow guidewire.

Second, the Examiner has not shown where Adams describes or suggests a drive shaft that includes a flattened and twisted distal tip and that is moveable between an axially retracted configuration and an axially extended configuration. In contrast, the burring tip of Adams comprises a rounded tip that comprises a plurality of curved flutes and cutting surfaces. (*See* Figure 2 of Adams). Such a distal tip is not flattened and twisted, as is required by claim 31.

Absent such showings, amended independent claim 31 and dependent claims 32-39 are allowable over Adams.

Claim rejections under 35 U.S.C. § 103(a) over Passafaro (6,156,046)

Claims 1, 20, 31, 67, and 80 are further rejected as allegedly being unpatentable over Passafaro et al. Such rejections are traversed as follows.

As noted above, independent claims 1, 20, 31, 67 and 80 recite assemblies/systems/kits that comprise *inter alia* a flexible, hollow guidewire that comprises an axial passage that receives a guidewire. Passafaro et al. also fails to describe or suggest such an assembly.

In rejecting the claims, the Examiner alleged:

> Passafaro et al disclose in figs 1, 1a, 2, 3, abstract and col. 11, lines 7-67, an assembly having all the limitation as recited in the above listed claims, including: a hollow guide wire (32); a rotating mechanism coupled to the drive shaft (52); wherein an actuator (42) coupled to the drive shaft (52); and wherein activation of the actuator advances the rotatable drive shaft (52) from a retracted position to an extended position; wherein said drive shaft (52) including a flattened and twisted distal tip (96, fig. 3) can be rotated and created (sic) a path through stenotic material. (emphasis added).

However, in reviewing the Passafaro et al. specification, it is clear that element 32 is a catheter and is not a guidewire. Importantly, Passafaro et al. actually positions a guidewire 46 within a lumen 50 of the catheter 32 to guide the catheter 32 to the occluding material. *See* col. 8, lines 31-49, col. 8, line50-59, and FIGS. 10A - 10M). It should be noted that Passafaro et al. describes in great detail how the guidewire 46 is a different structure from the catheter 32. Catheter 32 (which the Examiner equates to a "guidewire") is described at col. 14, lines 40-45 as:

> ...preferably configured to operate in an over-the-wire mode. The catheter 32 can be used with a conventional guidewire to form an initial pilot lumen equivalent to the outer diameter of the catheter 32 and the removal mechanism.

Based on such a description, a person of ordinary skill in the art would not consider such a catheter 32 to be a "guidewire," as the term is used in the art.

The present invention provides additional features to a guidewire that heretofore have not been provided. The guidewire assembly of the present invention allows for passing through total or near total occlusions and would thereafter allow a catheter to be passed through the occlusion. (*See for example* FIGS. 16A-18B and related discussion in Applicants'

application). Such an assembly is not described or suggested by Passafaro. In fact, Applicants' invention solves the problem that Passafaro et al. would still have. For example, as shown in FIG. 10A of Passafaro, if the occlusion was total or near total, the guidewire GW would not be able to pass through the occlusion to position the removal mechanism 54 and catheter 32. Unlike Passafaro et al., the guidewire assembly of the claims of the present invention allow the total or near total occlusion to be passed through. *See for example,* FIGS. 16A-18B of the present application, so that a catheter can be passed through the occlusion.

Because Passafaro et al. only describes a catheter having an axial passage and fails to describe or suggest a guidewire having an axial passage and a drive shaft in the axial passage, claims 1, 20, 31, 67 and 80 are also allowable over Passafaro et al.

Claim 75 is rejected under 35 U.S.C. §103(a) as being unpatentable over Adams in view of Noriega. Dependent claim 75 relies from allowable independent claim 67 and is therefore allowable.

Dependent Claims

In addition to relying on allowable independent claims, the dependent claims of the present invention provide novel aspects that aren't described or suggested by the cited references.

For example, dependent claim 9 recites that the assembly comprises a proximal housing that is removably coupled to the proximal end of the hollow guidewire. The removable proximal housing allows for a access system to be placed over the guidewire and advanced though the body lumen. (*See* page 19, lines 8-11 of the originally filed application). Such a removable proximal housing is not described or suggested by Adams. In contrast, Adams appears to show an integral outer hub. There is no description or suggestion that such a housing is removable.

Claim 14 recites that the distal tip of the drive shaft is radio-opaque. Such a distal tip is not described or suggested by Adams. Col. 10, lines 53-65 of Adams merely states that the distal aspiration port prevents accumulation of fluids and bone fragments at the distal tip so that there is enhanced endoscopic visualization of the bur tip during procedure. Such a description in Adams does not describe or suggest the radio-opaque distal tip recited in claim 14.

Claim 68 recites that the rotation of the shaped distal tip creates a profile that is at lest as large as the outer diameter of the hollow guidewire.

Claims 8, 36, and 72 recite that the distal end of the guidewire is steerable. As noted above, neither Adams nor Passafaro describe or suggest a steerable distal end.

CONCLUSION

Applicants respectfully request reexamination and reconsideration of the pending claims in this matter. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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